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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/611,741	07/01/2003	Adnan M.M. Mjalli	41305.287124	2564

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Charles W. Calkins
Kilpatrick Stockton LLP
1001 West Fourth Street
Winston-Salem, NC 27101-2410

EXAMINER

BADIO, BARBARA P

ART UNIT PAPER NUMBER

1617

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/611,741

Applicant(s)

MJALLI ET AL.

Examiner

Barbara P. Badio, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,11-15,29,30,32 and 33 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,2 and 11-15 is/are allowed.
- 6) ☒ Claim(s) 29,30,32 and 33 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

Nonfinal Office Action on the Merits

Specification

1. The disclosure is objected to because of the following informalities: Data is missing from page 44, section 0084 of the present specification.

Appropriate correction is required.

Oath/Declaration

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It was not executed in accordance with either 37 CFR 1.66 or 1.68.

Note: Petition to suspend rules in regard to having all inventors execute the Oath/Declaration was dismissed on July 11, 2005.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 29, 30, 32 and 33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a

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way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are (1) the nature of the invention, (2) the breadth of the claims, (3) the state of the prior art, (4) the predictability or unpredictability of the art, (5) the amount of guidance or direction presented, (6) the presence or absence of working examples, (7) the relative skill in the art and (8) the quantity of experimentation necessary. When the above factors are taken into consideration, the examiner's position is that one skilled in the art could not perform the invention commensurate in scope with the instant claim without undue experimentation.

Claims 29 and 30 recite "[a] method for the inhibition of the interaction of RAGE with its physiological ligands, which comprises administering to a subject in need thereof". The claims read on treatment of any disease, known and unknown, which might be treated by inhibiting the interaction of RAGE to any ligand, known and unknown. Claims 32 and 33 recite a number of non-related diseases not known to be treated utilizing a single agent.

The present specification discloses the inhibition of interaction of one of the claimed compound with NF- κ B (a RAGE ligand) (see section 0287 of the present specification). However, the present specification lacks any showing that said inhibition would result in treatment of any diseases and, thus, there is

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insufficient guidance for the skilled artisan to be able to utilize the claimed compounds in the treatment of the diseases that are encompassed by the instant claims.

Because the art lacks correlation between inhibition of the interaction of RAGE with its physiological ligands and treatment of the scope of diseases encompassed by the instant claims, the amount of experimentation necessary to practice the claimed invention would not be routine. The skilled artisan would have to first determine the ligands of RAGE not disclosed by the present specification before examining the effect of interaction between RAGE and all of its ligands in the development of each disease, known and unknown, before said artisan would begin the determination of the inhibition of said interaction on the treatment of each disease. Said determination would result in undue experimentation.

5. Claims 29, 30, 32 and 33 are rejected under 35 U.S.C. 112, first paragraph; as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Briefly, the instant claims are drawn to treating diseases caused by the interaction of RAGE with its physiological ligands utilizing the claimed compounds.

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The present specification discloses the inhibition of RAGE with one of its ligands (see section 0287). However, the present specification fails to provide sufficient descriptive information, such as correlation of inhibition of said interaction and treatment of a representative number of diseases and, thus, lacks adequate description of the presently claimed invention. In other words, the present specification does not reasonably convey to the skilled artisan in the art that at the time of the present application, applicant had possession of the claimed invention. Adequate written description requires more than a mere indication that interaction of RAGE and its ligands is "believed" to be a cause for certain diseases. Some correlation between inhibition of said interaction and treatment of a representative number of diseases is required.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 29 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims are indefinite for the following reason.

Claims 29 and 30 recite the inhibition of the interaction of RAGE with its physiological ligands by administration of the claimed compounds to a subject in need thereof. However, the claims lack recitation of the disease(s) to be treated. Therefore, it is unclear what disease(s) said subject has that would require

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administration of the claimed compounds. Thus, the metes and bound of the claimed invention is indefinite.

Allowable Subject Matter

8. Claims 1, 2 and 11-15 are allowed.

Other Matters

9. Update of the cross-reference section of the present specification is requested, i.e., Application 09/799,317 is not Patent No. 6,613,801.


Telephone Inquiry

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Barbara P. Badio, Ph.D.
Primary Examiner
Art Unit 1617

BB
July 25, 2005